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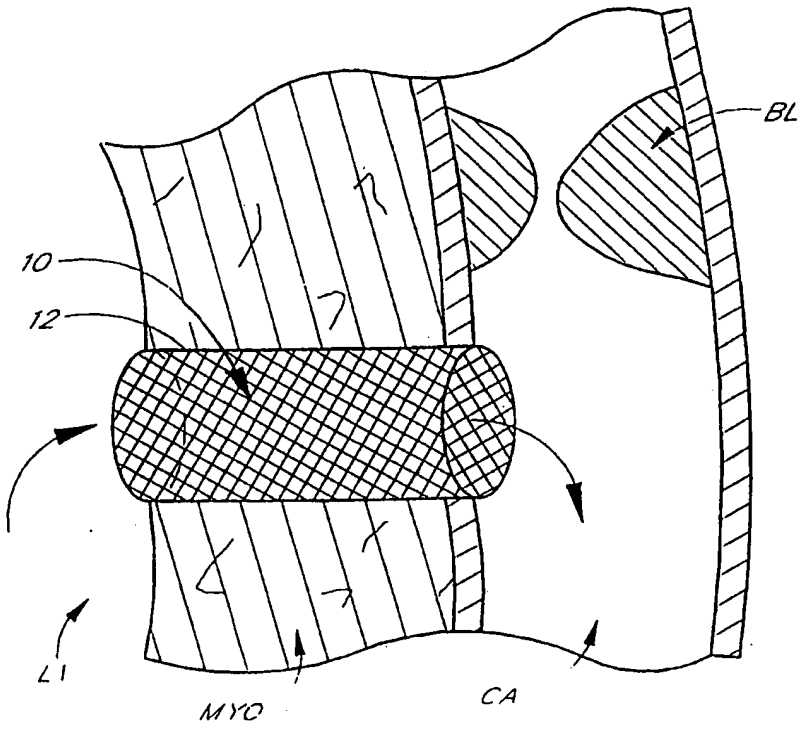
(54) Title: TRANSMYOCARDIAL SHUNT

(57) Abstract

Disclosed is a conduit that provides a bypass around an occlusion or stenosis in a coronary artery. The conduit is a tube adapted to be positioned in the heart wall to provide a passage for blood to flow between a heart chamber and a coronary artery, at a site distal to the occlusion or stenosis. The conduit has a section of blood vessel attached to its interior lumen which preferably includes at least one naturally occurring one-way valve positioned therein. The valve prevents the backflow of blood from the coronary artery into the heart chamber.



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TRANSMYOCARDIAL SHUNT

Field of the Invention

This invention relates to conduits that allow communication of fluids from one portion of a patient's body to another; and, more particularly, to a blood flow conduit to allow communication from a heart chamber to a vessel or vice versa, and/or vessel to vessel. Even more particularly, the invention relates to a left ventricular conduit and related conduit configurations having a blood vessel graft incorporated therein for controlling the flow of blood through the conduit to achieve bypass of an occluded or stenosed coronary artery.

Background of the Invention

Coronary artery disease is a major problem in the U.S. and throughout the world. Coronary arteries as well as other blood vessels frequently become clogged with plaque which, at the very least, can reduce blood and oxygen flow to the heart muscle (myocardium), and may impair the efficiency of the heart's pumping action, and can lead to heart attack (myocardial infarction) and death. In some cases, these coronary arteries can be unblocked through noninvasive techniques such as balloon angioplasty. In more difficult cases, a surgical bypass of the blocked vessel is necessary.

In a coronary bypass operation, one or more venous segments are inserted between the aorta and the coronary artery, or, alternatively, the distal end of an internal mammary artery is anastomosed to the coronary artery at a site distal to the stenosis or occlusion. The inserted venous segments or transplants act as a bypass of the blocked portion of the coronary artery and thus provide for a free or unobstructed flow of blood to the heart. More than 500,000 bypass procedures are performed in the U.S. every year.

Such coronary artery bypass graft (CABG) surgery, however, is a very intrusive procedure which is expensive, time-consuming, and traumatic to the patient. The operation requires an incision through the patient's sternum (sternotomy), and that the patient be placed on a heart-lung bypass pump so that the heart can be operated on while not beating. A saphenous vein graft is harvested from the patient's leg, another highly invasive procedure, and a delicate surgical procedure is required to piece the bypass graft to the coronary artery (anastomosis). Hospital stays subsequent to the surgery and convalescence are prolonged. Furthermore, many patients are poor surgical candidates due to other concomitant illnesses.

As mentioned above, another conventional treatment is percutaneous transluminal coronary angioplasty (PTCA) or other types of angioplasty. However, such vascular treatments are not always indicated due to the type or location of the blockage or stenosis, or due to the risk of emboli.

Thus, there is a need for an improved coronary bypass system which is less traumatic to the patient.

Summary of the Invention

The present invention addresses the need in the previous technology by providing a coronary bypass system which avoids a sternotomy and other intrusive aspects associated with coronary bypass surgery. It also frees the surgeon from having to perform multiple anastomoses, as is necessary in the current process.

The present device provides a conduit for diverting blood directly from a heart chamber, such as the left ventricle of the heart, to the coronary artery distal to the blockage or stenosis, thereby bypassing the blocked portion of the vessel. The conduit comprises a tube adapted to be positioned in the heart wall and having a section of blood vessel attached to the interior of the conduit, to provide a passage for blood flow which is similar to the body's own blood vessels.

The conduit device is delivered through the coronary artery to a position distal the blockage or stenosis. At that position, the coronary artery and the wall of the left ventricle, including the myocardium, are pierced to provide an opening or channel completely through from the coronary artery to the left ventricle of the heart. The conduit is then positioned in the opening to provide a permanent passage for blood to flow between the left ventricle of the heart and the coronary artery, distal to the blockage or stenosis.

The conduit is sized so that one open end is positioned within the coronary artery, while the other open end is positioned in the left ventricle. Prior to implantation of the conduit, a section of vein or other blood vessel is obtained from the patient, from another human donor, or from a nonhuman animal. The vein or other blood vessel is sized so as to fit within the interior of the conduit. The hollow lumen of the conduit with the blood vessel graft inserted therein provides a passage for the flow of blood.

If desired, the section of blood vessel inserted into the conduit may include one or more naturally occurring one-way valves. The valve prevents the backflow of blood from the myocardium into the left ventricle. For example, a section of vein having a valve therein can be used. Alternatively, the pulmonic valve or aortic valve

obtained from a nonhuman animal, such as a fetal pig or piglet, can be used to provide a one-way passage for the flow of blood through the conduit.

Brief Description of the Drawings

FIGURE 1A is a schematic, cross-sectional view of a human heart, showing a conduit in the myocardium of the heart for forming a bypass between the left ventricle and a coronary artery;

FIGURE 1B is an enlarged view of the bypass conduit of **FIGURE 1A**;

FIGURE 2 is an exploded view of a vein graft incorporated into a heart conduit in accordance with the preferred arrangement;

FIGURE 3 is a close-up, cross-sectional view of a blockage or stenosis in the coronary artery, illustrating the conduit of the preferred arrangement positioned so as to bypass the blockage or stenosis.

Detailed Description of the Preferred Embodiment

As is well known, the coronary artery branches off the aorta and is positioned along the external surface of the heart wall. Oxygenated blood that has returned from the lungs to the heart then flows from the heart to the aorta. Some blood in the aorta flows into the coronary arteries, and the remainder of blood in the aorta flows on to the rest of the body. The coronary arteries are the primary blood supply to the heart muscle and are thus critical to life. In some individuals, atherosclerotic plaque, aggregated platelets, and/or thrombi build up within the coronary artery, blocking the free flow of blood and causing complications ranging from mild angina to heart attack and death. The presence of coronary vasospasm, also known as "variant angina" or "Prinzmetal's angina," compounds this problem in many patients.

As used herein, the term "heart chamber" primarily refers to the interior, or lumenal, aspect of the left or right ventricle or the left or right atrium. The term "conduit," "stent," and "tube" herein refer to physical structures, preferably primarily artificial, that can be positioned between two or more chambers or vessels, to allow blood flow from one chamber or vessel to another. A "shunt" is any natural or artificial passage between natural channels, such as heart chambers or blood vessels. The conduit in the preferred arrangement can be made of a variety of materials, including various metals, such as nitinol, or plastics.

As used herein, the term "heart wall" comprises any one or more of the following portions or layers of the mammalian heart: the epicardium, myocardium, endocardium, pericardium, interatrial septum, and interventricular septum.

The principles of the present invention are not limited to left ventricular conduits, and include conduits for communicating bodily fluids from any space within a patient to another space within a patient, including any mammal. Furthermore, such fluid communication through the conduits is not limited to any particular direction of flow and can be antegrade or retrograde with respect to the normal flow of fluid. Moreover, the conduits may communicate between a bodily space and a vessel or from one vessel to another vessel (such as an artery to a vein or vice versa). Moreover, the conduits can reside in a single bodily space so as to communicate fluids from one portion of the space to another. For example, the conduits can be used to achieve a bypass within a single vessel, such as communicating blood from a proximal portion of an occluded coronary artery to a more distal portion of that same coronary artery.

In addition, the conduits and related methods can preferably traverse various intermediate destinations and are not limited to any particular flow sequence. For example, in one preferred embodiment of the present invention, the conduit communicates from the left ventricle or other heart chamber or coronary vessel, through the myocardium, into the pericardial space, and then into the coronary artery. However, other preferred embodiments are disclosed, including direct transmyocardial communication from a left ventricle, through the myocardium and into the coronary artery. Thus, as emphasized above, the term "transmyocardial" should not be narrowly construed in connection with the preferred fluid communication conduits, and other nonmyocardial and even noncardiac fluid communication are preferred as well. With respect to the walls of the heart (and more specifically the term "heart wall"), the preferred conduits and related methods are capable of fluid communication through all such walls including, without limitation, the pericardium, epicardium, myocardium, endocardium, septum, etc.

The bypass which is achieved with certain preferred embodiments and related methods is not limited to a complete bypass of bodily fluid flow, but can also include a partial bypass which advantageously supplements the normal bodily blood flow. Moreover, the obstructions that are bypassed may be of a partial or complete nature, and therefore the terminology "bypass" or "occlusion" should not be construed to be limited to a complete bypass or a complete occlusion but can include partial bypass and partial occlusion as described.

The preferred conduits and related methods disclosed herein can also provide complete passages or partial passages through bodily tissues. In this regard, the

conduits can comprise stents, shunts, or the like, and therefore provide a passageway or opening for bodily fluid such as blood. Moreover, the conduits are not necessarily stented or lined with a device but can comprise mere tunnels or openings formed in the tissues of the patient.

The conduits of the present invention preferably comprise both integral or one-piece conduits as well as plural sections joined together to form a continuous conduit. The present conduits can be deployed in a variety of methods consistent with sound medical practice including vascular or surgical deliveries, including minimally invasive techniques. For example, various preferred embodiments of delivery rods and associated methods are disclosed. In one embodiment, the delivery rod is solid and trocar-like. It may be rigid or semi-rigid and capable of penetrating the tissues of the patient and thereby form the conduit, in whole or in part, for purposes of fluid communication. In other preferred embodiments, the delivery rods may be hollow so as to form the conduits themselves (e.g., the conduits are preferably self-implanting or self-inserting) or have a conduit mounted thereon (e.g., the delivery rod is preferably withdrawn leaving the conduit installed). Thus, the preferred conduit device and method for installation is preferably determined by appropriate patient indications in accordance with sound medical practices.

In order to restore the flow of oxygenated blood through the coronary artery, the preferred arrangement provides for the shunting of blood directly from the heart to a site in the coronary artery which is distal the blockage or stenosis.

Although the specification herein will describe the conduit primarily with reference to the left ventricle, the preferred arrangement can be used with any of the four heart chambers, and with any coronary artery, including the left main coronary artery, the right coronary artery, the left anterior descending artery, the left circumflex artery, the posterior descending artery, the obtuse marginal branch or a diagonal branch.

A tunnel or opening is formed through the wall of the coronary artery and the myocardium and into the left ventricle of the heart which lies beneath, or deep to, the coronary artery. A conduit is positioned in the opening to keep it open.

The conduit may be introduced into the myocardium in a variety of ways, including by a catheter threaded through the femoral artery into the aorta and thence into the left ventricle and, if necessary, the left atrium; or by a catheter threaded through the femoral vein into the inferior vena cava and thence into the right atrium

and right ventricle. Alternatively, the conduit may be introduced through a surgical incision in chest wall (thoracotomy) or sternum (sternotomy).

Further details regarding conduits and conduit delivery systems are described in U.S. Patent Nos. 5,429,144 and 5,662,124.

The opening through the heart wall (including endocardium, myocardium, and epicardium) and coronary artery can be formed in a variety of ways, including by knife or scalpel, electrocautery, cryoablation, radiofrequency ablation, ultrasonic ablation, and the like. Other methods will be apparent to those of ordinary skill in the art.

The conduit is provided with a section of vein or other blood vessel positioned within its interior lumen. The section of vein or other blood vessel is obtained from the patient, from a donor, or from an animal. Prior to implantation of the conduit, a segment of blood vessel sized to fit with the lumen of the conduit is inserted into the conduit. The conduit with the graft therein provides a passage for the flow of blood which is similar to the natural human blood vessels. The segment of vein or other blood vessel harvested to fit within the conduit may include one or more of the valves which naturally occur in the human body. These valves act to prevent the backflow of blood. In the conduit, these naturally occurring venous valves prevent the blood from flowing back into the left ventricle of the heart from the coronary artery. The segment of vein is preferably inserted into the conduit prior to the conduit's deployment into the human body by any of various surgical or catheter-guided techniques known to those of skill in the art.

Referring now to **FIGURES 1A** and **1B**, a coronary artery bypass is accomplished by disposing a conduit 12 (**FIGURE 1B**) in a heart wall or myocardium MYO of a patient's heart PH (**FIGURE 1A**). The conduit 12 preferably extends from the left ventricle LV of heart PH to a clogged coronary artery CA at a point downstream of a blockage BL to create a passageway 8 therethrough. Conduit 12 is preferably made of a biocompatible material such as stainless steel or nitinol, although other materials such as Ti, Ti alloys, Ni alloys, Co alloys and biocompatible polymers may also be used. In one embodiment, conduit 12 has a one way valve 6 to allow blood to flow from the left ventricle LV to the coronary artery CA. Although the conduit 12 may elastically deform under the contractive pressure of the heart muscle during systole, the stent remains open to allow blood to pass from the patient's left ventricle LV into the coronary artery CA. During diastole, the blood pumped into

coronary artery through passageway 8 is blocked by one-way valve 6 from returning to left ventricle LV.

As shown in **FIGURE 2**, a preferred embodiment involves the use of a vein graft 10 taken from the patient. Prior to preparing the conduit 12 for placement in the patient, a section of vein 10 is obtained from the patient (i.e., an autologous graft or autograft). Of course, a blood vessel taken from another human donor (i.e., an allogeneic graft or allograft) or nonhuman animal species (i.e., a heterologous graft or xenograft) could also be used. The vein 10 is preferably taken from the saphenous vein in the leg of the patient. Alternatively, a donor vein could be used, or a fetal pig or piglet can be obtained and dissected to remove a section of the pulmonary artery having a pulmonic valve therein, or a section of the aorta having an aortic valve therein, or a similar vessel having a naturally occurring valve system. In other embodiments, the endothelial lining of a vein and/or a valve may be grown from one or more tissue cultures, utilizing cloning of donor cell lines or other genetic engineering techniques (or "tissue engineering") known to those of skill in the art. Thus, as used herein, "a section of blood vessel" may include one or more of the following: a surgically resected segment of a blood vessel, with or without one or more valves; the endothelial lining of a blood vessel, taken from an *in vitro* or *in vivo* specimen; and one or more venous valves, taken from *in vitro* or *in vivo* specimens.

As noted above, the section of vein 10 or other blood vessel harvested preferably contains one or more valves 14, which occur naturally in the veins. The section of vein 10 may also not have a valve. The vein section 10 is sized so as to be the same length as the conduit 12. The vein section 10 is placed within the interior lumen of the conduit 12 and attached to the inside of the conduit 12 by suturing or other attachment methods. The natural vein graft 10 is biocompatible and therefore reduces problems associated with rejection of the conduit 12 and clotting around or in the conduit 12. In addition, the vein 10 provides a natural valve system 14 that is already used throughout the human body to prevent the backflow of blood. In the case of a xenograft, treatment of the graft with chemicals, such as glutaraldehyde, may be undertaken to remove living cells, including antigenic materials, from the connective tissue framework of the graft so as to reduce thrombogenicity and antigenicity.

Referring now to **FIGURE 3**, a self-expanding conduit 12 having a section of vein 10 therein is introduced into the wall of the myocardium MYO as follows.

A conduit delivery catheter (not shown), having the compressed conduit 12 mounted on its distal end, is advanced over a puncture mechanism and into the wall of the myocardium MYO at a site distal to the blockage or stenosis BL in the coronary artery CA. When the conduit 12 is properly seated in the myocardial wall MYO, its retaining sheath is withdrawn, allowing the conduit 12 to expand and open a passageway, or maintain patency of the passageway, from the left ventricle of the heart LV to the coronary artery CA. This allows oxygenated blood to flow directly from the left ventricle of the heart LV through the conduit 12 and to the coronary artery CA, bypassing the section of coronary artery CA that is blocked BL, as shown by the arrows in **FIGURE 3**.

The conduit 12 may include attachment mechanisms not limited to hooks, barbs, large collars, and/or other methods to ensure that a seal is created between the coronary artery CA and the wall of the heart wall MYO, to prevent hemorrhaging and to prevent the threat of or actual conduit migration. When positioning and securing of the conduit 12 is completed, the remaining catheter assembly is removed, leaving the conduit 12 with the vein graft therein, in place in the body

The present vascular conduit having a blood vessel graft incorporated therein provides significant improvements in the present treatment of blockages or stenoses in the coronary artery. Although the invention has been described in its preferred embodiments in connection with the particular figures, it is not intended that this description should be limited in any way by the foregoing.

WHAT IS CLAIMED IS:

1. A coronary bypass conduit for implantation in a body of a patient comprising:

a hollow tube having an interior and an exterior and adapted to be positioned in a heart wall between a coronary vessel and a heart chamber; and

a section of a blood vessel positioned within said interior of said tube and adapted to allow blood to flow therethrough.

2. The conduit of Claim 1, wherein the section of blood vessel contains at least one naturally occurring valve.

3. The conduit of Claim 1, wherein the section of blood vessel contains at least one artificial valve.

4. The conduit of Claim 1, wherein the blood vessel is a human vein.

5. The conduit of Claim 1, wherein the section of blood vessel is an autograft.

6. The conduit of Claim 1, wherein the section of blood vessel is an allograft.

7. The conduit of Claim 1, wherein the section of blood vessel is a xenograft.

8. The conduit of Claim 1, wherein the section of blood vessel is developed through tissue engineering techniques.

9. The conduit of Claim 1, wherein said heart chamber is a left ventricle.

10. The conduit of Claim 1, wherein said heart chamber is a right ventricle.

11. The conduit of Claim 1, wherein said heart chamber is a left atrium.

12. The conduit of Claim 1, wherein said heart chamber is a right atrium.

13. The conduit of Claim 1, wherein said coronary vessel is a left anterior descending artery.

14. The conduit of Claim 1, wherein said coronary vessel is a right coronary artery.

15. The conduit of Claim 1, wherein said coronary vessel is a circumflex coronary artery.

16. The conduit of Claim 1, wherein said coronary vessel is a posterior descending artery.

17. A bypass conduit for implantation in a body of a patient comprising:

a hollow tube having an interior and an exterior; and

a section of blood vessel positioned within said interior of said tube and adapted to allow blood to flow therethrough.

18. A coronary bypass conduit for implantation in a body of a patient comprising:

a hollow tube having an interior and an exterior and adapted to be positioned in a heart wall between a coronary vessel and a heart chamber; and

means for permitting blood to flow through said tube in predominantly one direction.

19. The conduit of Claim 18, wherein the means for permitting blood to flow through said tube in predominantly one direction comprises a section of a blood vessel.

20. The conduit of Claim 19, wherein said blood vessel comprises a vein.

21. The conduit of Claim 19, wherein the section of blood vessel is an autograft.

22. The conduit of Claim 19, wherein the section of blood vessel is an allograft.

23. The conduit of Claim 19, wherein the section of blood vessel is a xenograft.

24. The conduit of Claim 19, wherein the section of blood vessel is developed through tissue engineering techniques.

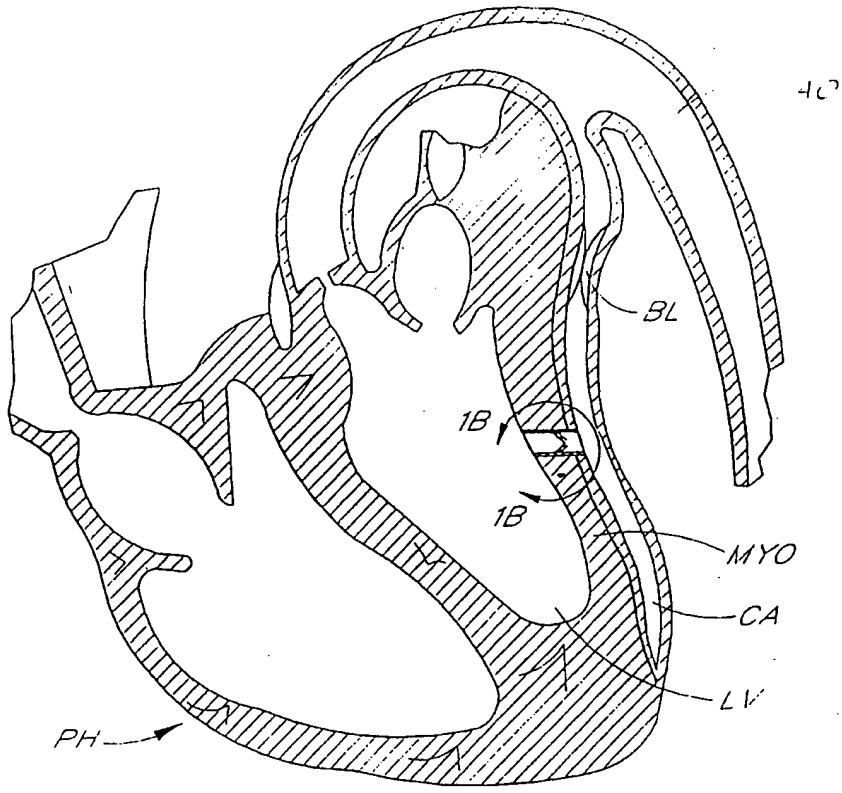

FIG. 1A

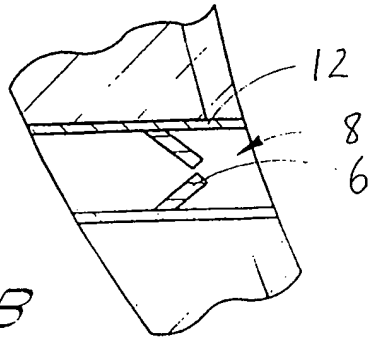

FIG. 1B

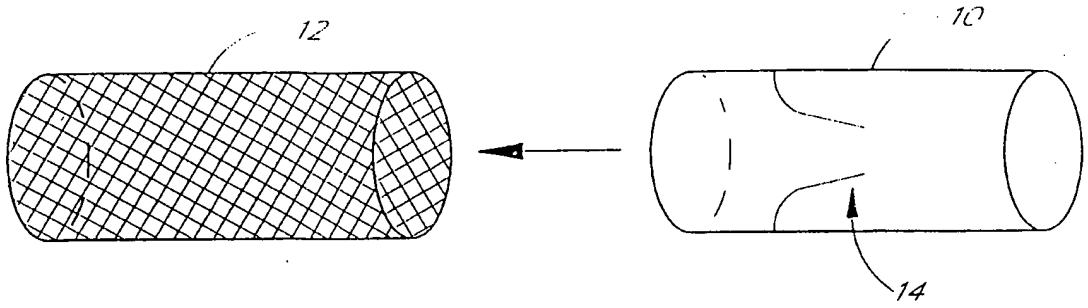

FIG. 2

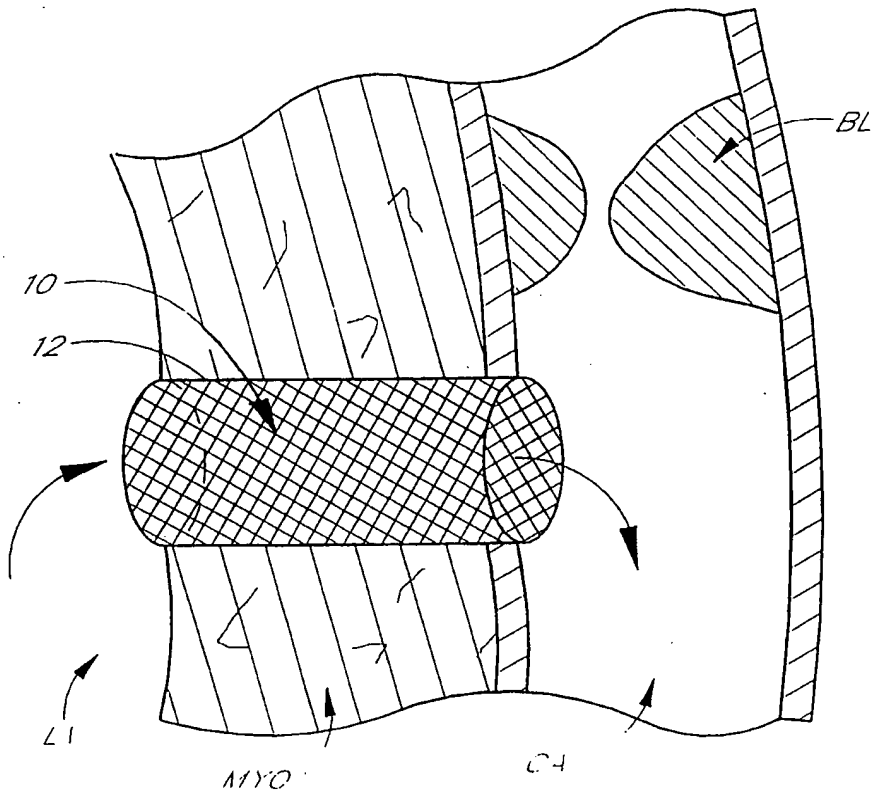

FIG. 3

INTERNATIONAL SEARCH REPORT

Int. Aional Application No
PCT/US 99/20736

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 99 36001 A (HEARTSTENT CORP) 22 July 1999 (1999-07-22) page 3, line 3 -page 5, line 3	1,2,4-24
X	WO 98 08456 A (TRANSVASCULAR INC) 5 March 1998 (1998-03-05) figures 1-8 page 12, line 26 -page 14, line 6 page 23, line 33 -page 24, line 25 page 25, line 16 -page 27, line 8 page 27, line 28 -page 33, line 3	18-21
A	-/—	1-5,9-17

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
21 January 2000	28/01/2000

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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Information on patent family members

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US 5655548 A	12-08-1997	AU 4352497 A	02-04-1998
		WO 9810714 A	19-03-1998
		US 5824071 A	20-10-1998

Patient Identification # _____ _____ _____ Patient Init ___ ___ ___
Study # Site # Pt #

FOLLOW-UP 3 mo

Date of Follow-up _____|_____|_____
dd | mm |yyyy

Follow-up not obtained ☐ _____Reason not obtained:

☐ Patient died ☐ Patient did not keep appointment ☐ Patient not contacted

Other, Please specify _____

Yes No

☐ ☐ Rehospitalization since last visit

Complete if "Yes"

Date	Duration	Reason for hospitalization	Device related?

Symptoms: None ☐

Please check all that apply:

Yes	No	
☐	☐	Fatigue
☐	☐	Dizziness
☐	☐	Dyspnea
☐	☐	Syncope
☐	☐	Palpitations
☐	☐	Chest Pain

CCS Angina Class: ☐0 ☐I ☐II ☐III ☐IV

NYHA _____☐ I ☐ II ☐ III ☐ IV

Physical examination

☐ Done Date _____|_____|_____ ☐ Not done
dd | mm |yyyy

Resting EKG

☐ Done Date _____|_____|_____ ☐ Not done
dd | mm |yyyy

Yes No dd | mm |yyyy

☐ ☐ New Myocardial infarction

If Yes:
☐Q-Wave ☐Non Q-Wave

Location on heart:

☐ Anterior wall
☐ Posterior wall
☐ Lateral wall
☐ Septum

PAS 1

Send the White sheet to Cardica, Keep the Yellow sheet in the patient binder

Patient Identification # _____ _____ _____ Patient Init ___ ___ ___
Study # Site # Pt #

FOLLOW-UP 3 mo

Stress EKG

☐ Done Date _____|_____|_____ ☐ Not done
dd | mm |yyyy

If Not Done specify why: ☐ Patient refused ☐ Other, Please specifiy: _____

Protocol _____

Maximum heart rate: _____ beats per minute

Maximum Blood Pressure: _____/_____

Yes No

☐ ☐ Angina or ischemic symptoms (what if there are no symptoms, but there is ischemia detected by EKG? I would ask the detected by EKG first and symptoms second, and not make them dependent.

If Yes:

Yes No

☐ ☐ Ischemia detected by EKG?

Coronary angiogram

☐ Done Date _____|_____|_____ ☐ Not done
dd | mm |yyyy

Yes No

☐ ☐ Angio CD/film sent to Cardica

☐ ☐ Angio report sent to Cardica

Echo Cardiogram

☐ Done Date _____|_____|_____ ☐ Not done
dd | mm |yyyy

Yes No

☐ ☐ Report sent to Cardica

Medications being taken at 3 mo:

Yes	No		Yes	No	
☐	☐	Aspirin	☐	☐	Antiarrhythmics
☐	☐	Warfarin / Coumadin	☐	☐	Diuretics
☐	☐	Ticlopidine / Clopidigrel	☐	☐	Other cardiac drugs (specify):
☐	☐	Lipid lowering drugs (specify):			_____
		_____	☐	☐	Other drugs (specify):
☐	☐	Beta blockers			_____
☐	☐	Calcium channel blocker	☐	☐	Contraceptives
☐	☐	Nitrates	☐	☐	Steroids
☐	☐	ACE-Inhibitors			

_____ _____|_____|_____

Signature of Investigator Date dd |mm |yyyy

PAS 2

Send the White sheet to Cardica, Keep the Yellow sheet in the patient binder